THUNDER TIGER CORP.
NO.7, 6th ROAD INDUSTRY PARK,
TAICHUNG, TAIWAN, R.O.C. 40755
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APR 2 7 2011

510(K) SUMMARY K10 2517

Tiger 500 Series High Speed Handpieces and Attachments

1. Date Summary Prepared: December 20,2010
2. Submitter Information

   510(k) Owner: THUNDER TIGER CORP.
   No.7, 6th Road, Industry Park, Taichung, 40755
   Taiwan, ROC

   Contact Person: Jo S.C. Lee/QA Engineer
   jo@thundertiger.com
3. Device Name

   ~~Trade Name: Tiger 500 Series High Speed Handpieces and Attachments~~

   Common Name: Dental Handpiece

   Classification Name: Handpiece, Air-Powered, Dental
   (21 CFR 872.4200, Product Code EFB)
4. Predicate Device: Dental Air-Powered Handpiece, models TIGER 300T, TIGER 300K, TIGER 300W, TIGER 300B, TIGER 300N (K062812)
   SUPERtorque High-Speed Handpieces (K073478)
   Tradition high speed Handpiece (K863677)
   Rapidd high speed Handpiece (K003518)
5. Device Description:

   The Tiger 500 series High Speed Handpieces and Attachments are similar to other high-speed dental handpieces currently on the US dental market in design, function, and intended use. The devices are air-powered handpieces that are reusable and ergonomically shaped, and are provided both with and without a fiber optic light system. The devices are supplied non-sterile, but must be sterilized before use, as with the predicate device. It will be packaged as a single-use bag. Several models could be connected to couplings of manufacturers including TTBIO, KaVo, NSK Mach, Sirona, and Star. According to IS07785-1:1997, Dental Handpiece-- Part 1: High-speed air turbine handpieces; and IS013485:2003, Medical Device Quality Management System to complete the device design steps.

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6. Intended Use:

Tiger 500 Series High Speed Handpieces are intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.

CAUTION: U.S. Federal law restricts the use of this device to licensed professionals.

7. Technological Characteristics:

The functions of Tiger 500 series High Speed Handpieces and Attachments were verified according to ISO7785-1. The substances of Tiger 500 series High Speed Handpieces are same as the predicate device in terms of its intended use, operating principles and functions.

8. Non-Clinical Performance/Safety Data:

The performance and safety of the Tiger 500 series High Speed Handpieces and Attachments are based upon conformity with applicable aspects of ISO 7785-1. Bench testing results demonstrate substantially equivalence. Therefore, we conclude that the both safe and effective for its intended use.

9. Substantial Equivalence

Substantial Equivalence Table	
TECHNOLOGICAL CHARACTERISTIC	COMPARISON TO PREDICATE
Intended use	Identical
Indications for use	Identical
Target population	Identical
Anatomical sites	Identical
Energy used and/or delivered	Similar
Human factors	Similar
Design	Similar
Performance	Similar
Standards met	Identical
Materials	Similar
Biocompatibility	Identical
Compatibility with environment and other devices	Identical
Sterility	Identical
Mechanical safety	Identical
Chemical Safety	Identical
Thermal safety	Identical
Radiation safety	Identical

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10. Conclusion:

The above descriptions coincide with the substantial equivalence made by Dental Air-Powered Handpiece, models TIGER 300T, TIGER 300K, TIGER 300W, TIGER 300B, TIGER 300N (K062812), SUPERtorque High-Speed Handpieces (K073478), Tradition high speed Handpiece (K863677) and Rapidd high speed Handpiece (K003518). They are same as the predicate device in terms of its intended use, operating principles and functions. Therefore, it can be seen that Tiger 500 series High Speed Handpieces are both safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Jo S.C. Lee
Quality Assurance Engineer
Thunder Tiger Corporation
No. 7, 6th Road Industry Park
Taichung
China (Taiwan) R.O.C. 40755

APR 27 2011

Re: K102517
Trade/Device Name: Tiger 500 Series High Speed Handpieces and Attachments
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece Accessories
Regulatory Class: I
Product Code: EFB
Dated: April 19, 2011
Received: April 21, 2011

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(K) Number (If Known): K102517

Device Name: Tiger 500 Series High Speed Handpieces and Attachments

Indications for Use:

Tiger 500 Series High Speed Handpieces and Attachments are intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

RSBetz DDS for Dr Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102517